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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,824	03/23/2005	Alain Rambach	37991-0035	6976

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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,824	RAMBACH ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 10, 2008 (IDS) & March 18, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-98* is/are pending in the application.

4a) Of the above claim(s) *29,30,35 and 37-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28, 31-34 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *29,30,35 and 37-98* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01-10-2008;5-4-2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of a request for reconsideration of a restriction requirement filed March 18, 2008 and an information disclosure statement filed January 10, 2008.

2. Claims 17-98 are pending in this application.

Claims 1-16 have been cancelled.

3. Applicant has elected with traverse Group I, product claims 17-51.

In addition, Applicant has elected species which are within the scope of claims 17-28, 31-34 and 36.

Claims 52-98 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions and claims 29-30, 35 and 37-51 have been withdrawn from consideration as being drawn to nonelected species , there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 18, 2008.

Restriction has been required under 35 U.S.C. 121 and 372 and is proper as stated since this application contains inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Restriction for examination purposes as indicated is proper because the inventions listed in previous action are independent or distinct for the reasons given and there would be a **serious search and examination burden** if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification with respect to the compound;

(b) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(c) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Claims 17-28, 31-34 and 36 are drawn to the elected invention and species. The restriction requirement has been made **FINAL.**

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The objection under 35 U.S.C. 132(a) because it introduces new matter into the disclosure has been withdrawn and Invention I has been examined.

6. **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-28, 31-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the art of record in A or B as submitted:

A. Claims **17-28, 31-34 and 36** stand rejected for the product claims over the art of record as stated in the final rejection dated July 11, 2007,

B. Claims **17-28, 31-34 and 36** stand rejected for the product claims over the art of record as stated in the reference submitted in the IDS Jan 10, 2008 "BECKER& Associates OPPO023 GROUNDS FOR OPPOSITION ON BEHALF OF BIORAD] PASTEUR, AGAINST EP 1 543 147 (ALAIN RAMBACH);

each alone further in view of Bochner et al , 5,989,853; 6,436,631 or 6,696,239 and Gosnell et a l U.S. 6,130,057.

l The factual inquiries set forth in *Graham* **v.** *John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The claimed subject matter was considered to be prima facie obvious based on the art as submitted in A [Final Rejection]and B[Opposition]. However, the new instant

claims are drawn to the same subject matter with an additional new limitation that the culture medium is a "gelled culture medium" which references lacks this limitation.

The references of record do not anticipate the claimed inventions. In addition, the references alone or further in view of each other do not suggest or motivate one of ordinary skilled in the art to employ a gelled culture medium which contains the specific claimed antibiotics.

However, References to Bochner 5,989,853; 6,436,631 or 6,696,239 and Gosnell et al U.S. 6,130,057 teach gelled culture mediums

Bochner U.S. 6,696,239 discloses the following:

Bochner teaches the use of a gelled medium as recited:

> "The situation is particularly desperate in the area of nosocomial infections, as infections with methicillin-resistant Staphylococcus aureus (MRSA)
>
> It is contemplated that the kit may include reagents such as BACs, carbon sources, nitrogen sources, chromogenic substrates, diluents and other aqueous solutions, as well as specialized microplates (e.g., GN, GP, ES, YT, SF-N, SF-P. and other MicroPlates.TM., obtained from Biolog), inoculants, miniaturized testing cards (e.g., MicroCards.TM.), and plated **agar media**.
>
> As used herein the term "gel-initiating agent" refers to any compound or element which results in the formation of a gel matrix, following exposure of a gelling agent to certain conditions or reagents. It is intended that "gel-initiating agent" encompass such reagents as cations (e.g., Ca.sup.2+, Mg.sup.2+, and K.sup.+). Until the gelling agent contacts at least one gel-initiating agent, any suspension containing the gelling agent remains "ungelled" (i.e., there is no thickening, increased viscosity, nor hardening of the suspension).

> After contact, the suspension will become more viscous the invention **provides numerous advances and advantages** over the prior art, including: (1) much greater safety, as there is no spillage, nor aerosolization of cells, mycelia, nor spores, while performing or inoculating test wells; (2) faster biochemical reactions are produced, giving final results hours or days earlier than commonly used methods; (3) more positive biochemical or phenotypic reactions are obtained, giving a truer picture of the microorganisms' metabolic characteristics; (4) darker, more clear-cut biochemical reactions and color changes are obtained; (5) more uniform color and/or turbidity are obtained, as the cells, mycelia, and/or spores do not settle and clump together at the bottom of the wells, nor do they adhere to the sides of the wells; (6) the reactions are much easier to observe visually or with optical instruments (e.g., the Biolog MicroStation Reader.TM.); and (7) the overall process for performing multiple tests is extremely simple and efficient, requiring very little labor on the part of the biologist. All of these advantages enhance the speed and accuracy of scoring test results in studies to perform comparative phenotype analysis for the assessment of BACs using any cell type, including microbial strains. and may or may not form a rigid gel (i.e., contact will produce "gelling")."

Bochner..U.S. 5,989,853

Bochner teaches the advantages of utilizing a gel matrix for the testing of microorganisms which includes S. aureus:

> The present invention relates to growing and testing microorganisms in a multitest format which utilizes a gel forming matrix for the rapid screening of clinical and environmental cultures. The present invention is suited for the characterization of commonly encountered microorganisms (e.g., E. coli, S. aureus, etc.), as well as commercially and industrially important organisms from various and diverse environments (e.g., the present invention is particularly suited for the growth and characterization of the actinomycetes and fungi).

Gosnell et al U.S. 6,130,057

Gosnell et al teaches the following:

> "The following bacteria were evaluated: ....Staphylococcus aureus .....

> "Culture media for microorganisms containing blood or hemin, particularly Trypticase Soy Agar with blood, and chocolate agar, are combined with known chromogenic substrates to produce chromogenic media. Methods for preparing these chromogenic media include adding chromogenic substrates to the surface of previously prepared media, or incorporating the chromogenic substrate into the media as it is prepared. Methods for distinguishing microorganisms in a sample using these culture media are also described."
>
> Identification and differentiation of different species of yeasts can be accomplished using CHROMagar Candida plates available from CHROMagar Company, Paris, France. Yeasts from clinical samples grown on these plates are identified by variant colors and morphology. See e.g. A. P. Koehler, et al. J. Clin. Microbiol., 37, pp. 422-26 (1999). The CHROMagar medium is composed of 10 g peptone, 20 g glucose, 15 g agar, 0.5 g chloramphenicol, per liter, and a "chromogenic mixture," whose components are maintained in secrecy by the manufacturer.

Gosnell et al teaches the combination of suitable chromogenic substrates as noted on columns 6 and 7 which includes the chromogenic agent of claims 19-20, see Example 1, line 63; claims 21-24, see Example 1, line 54.

It would have been prima facie obvious to one of ordinary skilled in the art to employ a gelled culture medium containing agar as taught by **Bochner** for the agar of **Gosnell et a**l in combination with any one of a number of chromogens for the testing of Staphyloccus aureus in the presence of cefoxitin as taught by the references of A or B.

Further in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007) based on the reasoning may still include the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it. However, the Guidelines explain that there is no requirement that patent examiners use the TSM approach in order to make a proper obviousness rejection. Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention that invention may still be found obvious.

If there are any differences with respect to the claimed subject matter and the general knowledge pertaining to the art in the area, that these differences would have been prima facie obvious to one of ordinary skilled in the pertinent art whether it was based on the art of record or claimed subject would have obvious for the "combination of familiar elements according to known methods is likely to be obvious when it does no

more than yield predictable results" as in this instant application based on the above art record.

Thus, the prior art in combination does teach, suggests and motivates one that the claimed limitations would have been obvious to one of ordinary skill in the art absent a showing of patentable subject matter.

7. **No claim is allowed.**

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HERBERT J. LILLING whose telephone number is 571-272-0918. The examiner can normally be reached on WORK AT HOME MAXIFLEX.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JON WEBER can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
May 31, 2008

/HERBERT J LILLING/
Primary Examiner Art Unit 1657